IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	§	**MDL No. 2545** **Master Docket Case No. 1:14-cv-01748** **Honorable Matthew F. Kennelly**
CHRISTOPHER CHAUDOIR Plaintiff , VS AUXILIUM PHARMACEUTICALS, INC.; DPT LABORATORIES, LTD.; ABBVIE, INC., ABBOTT LABORATORIES, INC.; ACTAVIS PLC; and ACTAVIS, INC. F/K/A WATSON PHARMACEUTICALS, INC. ACTAVIS PHARMA, INC.; and WATSON LABORATORIES, INC., Defendants.	§	COMPLAINT AND JURY DEMAND Civil Action No.: 1:15-cv-975

COMPLAINT

Plaintiff, Christopher "Chris" Chaudoir, (hereinafter "Plaintiff"), an individual of the full age of majority and resident of Lafayette, Lafayette Parish, Louisiana, complaining against Defendants: Auxilium Pharmaceuticals, Inc., DPT Laboratories, Inc.; AbbVie, Inc., and Abbott Laboratories, Inc.; Actavis PLC, and Actavis, Inc. f/k/a: Watson Pharmaceuticals, Inc., (hereinafter "Defendants") states as follows:

I. PROCEDURAL AND FACTUAL BACKGROUND

A. INTRODUCTION

1. This case involves the prescription drugs Testim 1% gel, AndroGel 1% and Testosterone-Cypionate injections (generic) which Defendants, Auxilium Pharmaceuticals, Inc.; DPT Laboratories, Inc.; AbbVie, Inc., Abbott Laboratories, Inc., Actavis PLC and Actavis, Inc. f/k/a: Watson Pharmaceuticals, Inc. (Hereinafter jointly referred to as "Defendants" or "manufacturers") manufacture, sell, distribute and promote as testosterone replacement therapies.

2. Defendants misrepresented that Testim, Testosterone Cypionate, and AndroGel are safe and effective treatments for hypogonadism and a condition they referred to as "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thromboembolic events.

3. Testim, Testosterone Cypionate, and AndroGel are exogenous forms of the androgen testosterone. They regulate the expression of platelet TXA_2 receptors in humans, which significantly increases platelet aggregation. They cause an increase in hematocrit and estradiol in adult males, resulting in thickened blood, the development of blood clots, and heart damage. These effects, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries.

4. Testosterone Cypionate (Generic) is an androgenic hormone testosterone replacement drug delivered via intramuscular injection. It is available in two strengths: 100 and 200 mg/mL.

5. Testim and AndroGel are delivered transdermal and applied to the skin in the form of a gel. They are available in either a 1% or 1.62% concentrations.

6. Defendants failed to adequately warn physicians about the risks associated with the Testim, Testosterone Cypionate, and AndroGel and the monitoring required to insure their patients' safety.

7. Defendants engaged in marketing and advertising campaigns for Testim, Testosterone Cypionate, and AndroGel, including aggressive unbranded "disease awareness" campaigns to alert men that they might be suffering from "low testosterone."

8. Defendant's wrongful acts, omissions, inadequate warnings and misrepresentations caused and/or were substantial factors in Plaintiff, Christopher Chaudoir s injuries, damages, and losses.

9. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said products and thereby actively participated in the tortious conduct which resulted in the injuries, damages and losses suffered by Plaintiff herein.

10. According to the industry-leading Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include being "sad or grumpy," "experiencing deterioration in the ability to play sports," and "falling asleep after dinner." *Available at*: http://www.isitlowt.com/do-you-have-low-t/low-t-quiz. Most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural aging process.

11. Defendants further benefitted from and acted in concert with their competitors' marketing and advertising efforts to create a disease known as "Low T" by asking doctors to prescribe Testim, Testosterone Cypionate, and AndroGel when their patients, convinced they had "low testosterone" asked for a testosterone replacement therapy (TRT) prescription.

12. The FDA has not approved any testosterone replacement therapy drug as a treatment for low testosterone or "Low T". Additionally, low testosterone is not a disease recognized by the medical community. Instead, it is a normal result of the aging process experienced by the majority of males.

13. Because of this "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, diagnoses of "Low T" have increased exponentially.

14. Consumers of Testim, AndroGel and Testosterone Cypionate, and their physicians relied on the companies' false representations and were misled as to the drugs' safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thromboembolic events.

B. PARTIES

15. **Plaintiff, Christopher Chaudoir** is and was at all times relevant hereto, a resident of the full age of majority (DOB 12/29/1967) and citizen of Lafayette, Lafayette Parish, Louisiana.

16. **Defendant, Auxilium Pharmaceuticals, Inc.** is a Delaware corporation which has its principal place of business at 640 Lee Road, Chesterbrook, Pennsylvania 19087.

Plaintiff avers that Auxilium conducted business and derived substantial revenue from sales of Testim® within the State of Louisiana.

17. **Defendant, DPT Laboratories, Ltd**. is a limited partnership existing under the laws of Texas with its principal place of business at 318 McCullough, Ocean County, San Antonio, Texas 78215. At all times pertinent herein, Testim was manufactured by DPT Laboratories, Ltd. for Auxilium Pharmaceuticals, Inc. at its San Antonio, Texas facility.

18. **Defendant, AbbVie, Inc**. is a corporation organized and existing under the laws of Delaware with its principal place of Business at 1 North Waukegan Road, North Chicago, Lake County, Illinois 60064.

19. **Defendant Abbott Laboratories, Inc**. is a corporation organized and existing under the laws of the state of Illinois and maintains its principal place of business at 100 Abbot Park Road, North Chicago, Lake County, Illinois 60064.

20. **Defendant Watson Pharmaceuticals, Inc**., ("Watson") is a corporation organized and existing under the laws of the State of New Jersey and maintains a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054 and at all times relevant to this cause of action was engaged in the business of designing, testing, studying, researching, evaluating, endorsing, formulating, compounding, manufacturing, producing processing, assembling, inspecting distributing marketing, labeling, promoting, advertising, packaging, selling, prescribing, or otherwise placing Testosterone Cypionate in the stream of interstate commerce of the United States, including Louisiana. Defendant Watson Pharmaceuticals, Inc. may be served at Legal Department, Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NY 07054.

21. **Defendant Actavis PLC** is a foreign corporation organized and existing under the laws of Ireland with its global headquarters located at 1 Grand Canal Square, Docklands,

Dublin 2, Ireland. Actavis Plc also has administrative headquarters located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. At all relevant times herein, Actavis, Plc was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Testosterone Cypionate, in the State of Louisiana.

22. **Defendant Actavis, Inc.**, a wholly-owned subsidiary of Actavis Plc, and formerly known as Watson Pharmaceuticals, Inc., is a domestic corporation organized and existing under the laws of Nevada with its principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

23. By way of background, Watson Pharmaceuticals, Inc. acquired Actavis Group in 2012 and announced shortly afterward that it would change its name to Actavis, Inc. as of January 2013. Watson Pharmaceuticals, Inc. acquired TheraTech, Inc., the original manufacturer of Testosterone Cypionate, in 1999. At all times relevant herein, Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Testosterone Cypionate, in the State of Louisiana.

24. **Defendant Actavis Pharma, Inc**., formerly known as Watson Pharma, Inc., is a corporation organized and existing under the laws of Delaware with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. At all times relevant herein, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Testosterone Cypionate, in the State of Louisiana.

25. **Defendant, Watson Laboratories, Inc.,** is a domestic corporation organized and existing under the laws of Nevada with its principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. At all times relevant herein, Watson Laboratories, Inc., a subsidiary of Actavis PLC, was

engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Testosterone Cypionate, in the State of Louisiana.

26. By way of background, Unimed Pharmaceuticals Inc. originally developed AndroGel and sought FDA approval in 1999. Before the drug was approved by the FDA in 2000, Solvay Pharmaceuticals Inc. acquired Unimed Pharmaceuticals, Inc. and subsequently brought AndroGel to market. In 2010, Defendant Abbott Laboratories, Inc. acquired Solvay's pharmaceutical division which included AndroGel. Then in 2013, Abbott Laboratories, Inc. created AbbVie, Inc., a company composed of Abbott's former proprietary pharmaceutical business, which included AndroGel.

27. At all times herein mentioned, Defendants, in interstate commerce and in this judicial district, advertised, promoted, supplied, and sold to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public certain pharmaceutical products, including, Testim, AndroGel and Testosterone Cypionate.

C. JURISDICTION AND VENUE

28. Subject matter of this action arises under 28 U.S.C. § 1332. The parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

29. Pursuant to Paragraph B. (i.) (b.) of Case Management Order No. 12 entered by this honorable Court in MDL No. 2545, on October 24, 2014; all rights as to personal jurisdiction of the Defendants: Auxilium Pharmaceuticals, Inc.; DPT Laboratories, Inc.; AbbVie, Inc., Abbott Laboratories, Inc., Actavis PLC, and Actavis, Inc. f/k/a: Watson Pharmaceuticals, Inc., as well as, venue, forum convenience and *Lexecon* are reserved. In the interim, this matter is presumed to have been filed in the United States District Court in and for the Western District of Louisiana where plaintiff, Christopher Chaudoir, resides.

30. Plaintiff avers that venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because, inter alia, a substantial part of the conduct, events and/or omissions giving rise to the Plaintiff's claims occurred in, and because the Defendants transact business in, this district.

31. This Court has supplemental jurisdiction over any corollary state claims pursuant to 28 U.S.C. § 1367.

D. FACTUAL BACKGROUND

1. General Allegations

32. This action is for damages and is brought on behalf of Plaintiff, Christopher Chaudoir, who was prescribed and supplied with, received and who has injected and applied the prescription drugs , Testim, AndroGel and Testosterone Cypionate, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable the Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by these drugs.

33. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused or were substantial contributing factors in causing Plaintiff's injuries, damages, and losses.

34. At all times herein mentioned, the Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for

sale or selling the prescription drugs Testim, AndroGel and Testosterone Cypionate for the use and application by men, including, but not limited to Plaintiff.

35. At all times herein mentioned, Defendants were authorized to do business within the states of Louisiana and Illinois.

36. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said products and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

37. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs caused the appreciable harm sustained by him. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drugs Testim, AndroGel and Testosterone Cypionate are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

2. Regulatory History and Approved Uses

38. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

39. In men, testosterone levels normally begin a gradual decline after the age of thirty.

40. The average testosterone levels for most men range from 300 to 1,000 ng/dl of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who may have testosterone levels below 300 ng/dl on one day will have normal testosterone levels the next. Additionally, testosterone levels gradually decline as men age. This decline in serum testosterone levels is a normal process that does not represent a medical condition or disease.

41. The Food and Drug Administration approved Testim, and AndroGel and/or Testosterone on or about February 28, 2000 for the treatment of adult males who have low or no testosterone (a condition called Hypogonadism) in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy. The FDA approved Testosterone Cypionate on November 23, 2010. After FDA approval, Testim, Testosterone Cypionate, and AndroGel have been widely advertised and marketed by Defendants as safe and effective testosterone replacement therapies.

42. Hypogonadism is a specific and recognized condition of the endocrine system, which in men may involve the severely diminished production or nonproduction of testosterone. Primary hypogonadism occurs under circumstances of congenital or acquired pathologic insults to and conditions of the testes in men. Secondary hypogonadism occurs under circumstances of hypogonadotropism, including hypothalamic-pituitary diseases and

disorders and other conditions which cause suppression of gonadotropin-releasing hormone (GnRH).

43. At all times material hereto, Defendants knew and understood the FDA-approved indications for clinical use of the Testim, Testosterone Cypionate, and AndroGel products.

44. There have been a number of studies concluding that testosterone therapy causes a sudden increase in hematocrit, hemoglobin and estradiol, and associating its use with increased the risk of heart attacks and strokes. Defendants, knew or in the exercise of reasonable care should have known that their products, Testim, Testosterone Cypionate, and AndroGel were defectively designed, unreasonable dangerous in normal use, and highly likely to cause injury or death, but they failed to provide adequate warnings about these known risks.

3. Direct to Consumer Marketing and Promotion to Physicians for Unbranded/Off-Label Use.

45. Defendants expanded the indications for use of their testosterone replacement therapy (TRT) drugs by promoting and detailing "Low T" as an acquired form of hypogonadism, and took advantage of intentional ambiguity in the Testim, Testosterone Cypionate, and AndroGel product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians.

46. In 2000, when reviewing the TRT drug advertisements, the FDA told Defendants that "claims and representation that suggest that testosterone replacement therapy is indicated for men with 'age-associated' hypogonadism or 'andropause' are misleading." The drug, the FDA said, was only approved for men with hypogonadism. Despite this admonition from the FDA, Defendants have continued to market and promote testosterone replacement therapy for "andropause" and "Low T".

47. Testim, Testosterone Cypionate, and AndroGel may produce undesirable side effects to patients who use the drugs, including but not limited to, myocardial infarction, stroke, and death.

48. In some patient populations, Testim, Testosterone Cypionate, and AndroGel use may increase the incidence of myocardial infarction and death by over 500%.

49. In addition to the above, Testim, Testosterone Cypionate, and AndroGel have been linked to several severe and life changing medical disorders. Patients taking testosterone may experience enlarged prostates and increased serum prostate-specific antigen levels.

50. Defendants' marketing strategy beginning in 2000 has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of their products.

51. Defendants' advertising programs sought to create the image and belief by consumers and their physicians that the use of testosterone injections was a safe method of alleviating their symptoms, had few side effects, and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendant had no reasonable grounds to believe them to be true.

52. Defendants purposefully downplayed, understated, and outright ignored the health hazards and risks associated with using testosterone. Defendants deceived potential testosterone users by relaying positive information through the press, including Testim, Testosterone Cypionate, and AndroGel testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

53. As a result of Defendants' advertising and marketing, and representations about their products, men in the United States pervasively seek out prescriptions for testosterone. If Christopher Chaudoir had known the risks and dangers associated with testosterone replacement therapy, he would not have

taken testosterone and consequently would not have been subject to its serious side effects and ultimately death.

54. In particular, in the warnings given by Defendants, and other testosterone replacement therapy drug manufacturers in their commercials, product materials, online and print advertisements, and overall mutually beneficial marketing campaigns failed to mention any significant cardiac or stroke side effects and falsely represent that these drug manufacturers adequately tested their respective products for all likely side effects.

55. Christopher Chaudoir was prescribed and used as directed Testim, AndroGel and Testosterone Cypionate, for symptoms his doctor attributed to low testosterone as a result of Defendants' advertisements, actions and inactions.

56. After taking periodic doses of Testim and/or AndroGel and/or Testosterone Cypionate from approximately March 1, 2008 through March 2014, Christopher Chaudoir was required by his physician to undergo an angiogram. On or about March 31, 2014 Plaintiff, Christopher Chaudoir, was informed that this diagnostic procedure revealed evidence of two prior infarctions dating back to September 2011 and he was instructed to cease and desist from ingesting any further TRT drugs.

57. Prior to using the TRT drugs manufactured, marketed and sold by Defendants, Christopher Chaudoir had no significant history of cardiovascular issues.

58. Plaintiff, Christopher Chaudoir, has and will sustain significant general and special injuries, damages and losses, including medical expenses, lost wages, diminished economic horizons, and other items of recoverable damages for which he seeks maximum recovery as a matter of law.

59. Had Defendants properly disclosed the risks associated with the use of their TRT products, Plaintiff would have avoided the risk of cardiac injury by either not using testosterone replacement therapy at

all, severely limiting the dosage and length of use, and/or by closely monitoring the degree to which the drugs were adversely affecting his health.

60. Since the FDA approved Testim, Testosterone Cypionate, and AndroGel for a very specific medical condition called Hypogonadism, Defendants have also sought to convince primary care physicians that Hypogonadism is synonymous with "Low T" and that low testosterone levels are widely under-diagnosed, and that normal and common conditions associated with normal aging could be caused by low testosterone levels.

61. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy has been available for years, millions of men who have never been prescribed testosterone continue to flock to their doctors and pharmacies.

62. Defendants manufactured, promoted and sold these drugs to treat a non-existent medical condition that they call "Low T", a name created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, Defendants marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

63. As observed by Lisa M. Schwartz, M.D., M.S. and Steven Woloshin, M.D., M.S. in their article "Low T as a Template: How to Sell Disease" published in JAMA Internal Medicine 173(15):1460-1462 (August 12/26, 2013) concerning the "Low T" campaigns by the pharmaceutical industry:

    i. Whether the campaign is motivated by a sincere desire to help men or simply by greed, we should recognize it for what it is: a mass, uncontrolled experiment that invites men to expose themselves to the harms of a treatment unlikely to fix problems that may be wholly unrelated to testosterone levels.

ii. We agree with Braun that there is a strong analogy between the marketing of testosterone therapy for men and estrogen therapy for menopausal women. Ignoring the lessons of estrogen therapy is scandalous. Before anyone makes millions of men aware of Low T, they should be required to do a large-scale randomized trial to demonstrate that testosterone therapy for healthy aging men does more good than harm.

64. Sales of Testosterone replacement therapies have more than doubled since 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, Are Testosterone Drugs the Next Viagra? May 10, 2012, Bloomberg Businessweek, available at: http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

65. In 2009 a whistle-blower lawsuit filed by relator John King and Jane Doe on behalf of the United States and 23 individual states alleged that testosterone was marketed and promoted for off-label uses, including osteoporosis, sexual dysfunction, depressions and obesity.

66. The Defendants engaged in aggressive promotion to physicians that testosterone replacement therapy could be used as a lifestyle drug to treat conditions such as erectile dysfunction. Sales representatives were instructed to tell physicians that if a patient requested medication for erectile dysfunction the physician should first test the patient's testosterone level to determine if the cause of the erectile dysfunction was "Low T".

67. The marketing program sought to create the image and belief by consumers and physicians that low testosterone was an actual disease or medical condition that affected a large number of men in the United States, and that the use of Testim, Testosterone Cypionate, and AndroGel is safe for human use as a treatment for "Low T", even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.

68. At all times material hereto, Defendant's marketing strategy included the use of sales or drug detailing representatives ["reps"] and marketing and brand team personnel who performed on-line and in-person Testim, Testosterone Cypionate, and AndroGelproduct detailing to physicians; and, promotional and detailing to healthcare providers and physicians at medical organization and society meetings and conventions via display booths, sponsored meeting sessions and "satellite" sessions, and sponsored medical speakers.

69. Defendants' drug "reps" detailed and marketed Testim, Testosterone Cypionate, and AndroGel to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

70. Defendants denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

71. The Defendants knew and understood the meaning of the terms "off-label" and "label expansion."

72. The Defendants knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

73. Defendants marketed, promoted, and detailed Testim, Testosterone Cypionate, and AndroGel for "off-label" use for the purpose of "label expansion," and detailed and promoted the products to physicians, and advertised the product to consumers and patients, under the rubric that "Low T" was an indication for clinical use of the Testim, Testosterone Cypionate, and AndroGel.

74. A manufacturer may not introduce a drug into interstate commerce with intent that it be used for an "off-label" purpose.

75. A manufacturer misbrands a drug if the labelling, or any of the manufacturer's promotional and advertising materials, describe an intended use for the drug that has not been approved by the FDA.

76. Promotional materials are misleading if they suggest that a drug is useful in the treatment of a broader range of conditions, or in a broader population of patients, than has been demonstrated by substantial evidence or substantial clinical experience.

77. Promotional materials are misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

78. Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made, or with respect to the consequences that may result from the use of the drug as recommended or suggested by the materials.

79. The FDA did not, and never has, approved Testim, Testosterone Cypionate, and AndroGel for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or,

g. bone strength or density abnormalities.

4. Adverse Events and Serious Health Risks Caused by TRT.

80. There have been a number of studies associating testosterone use in men with an increased risk of serious injuries from blood clots and cardiovascular events.

81. Testosterone replacement therapy involves the administration of exogenous testosterone into the male body in an attempt to raise the serum level of total testosterone. This is achieved through application of a cream, gel or patch directly to the skin for transdermal absorption into the body. It can also be delivered into the body (as here) by subcutaneous injection or placement of a time-released pellet containing the drug.

82. The absorption of exogenous testosterone into the male body can cause an increase in serum levels of testosterone, and it also results in an increase in hematocrit[1] and serum estradiol levels[2]. It can also cause increased platelet aggregation and vasoconstriction.

83. Hematocrit is the proportion of total blood volume that is comprised of red blood cells. Erythrocytosis is an increase in the number of circulating red blood cells especially resulting from a known stimulus (like Testosterone). When a person's hematocrit level is raised through erythrocytosis, the resulting condition is called polycythemia, which simply means an elevated red blood cell count. The range for normal hematocrit levels in adult males is 44%-48%.

84. The administration of exogenous testosterone causes a 7%-10% increase in hematocrit levels in adult males through the process of erythrocytosis.[3] An increase of hematocrit that is 7%-10% above normal range is a significant elevation and qualifies as

[1] Fernandez-Balsells, M., et al., Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis. J Clin Endocrinol Metab, June 2010, 95(6):2560–2575.
[2] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.
[3] Bachman, E., et al. Testosterone Induces Erythrocytosis via Increased Erythropoietin and Suppressed Hepcidin: Evidence for a New Erythropoietin/Hemoglobin Set Point. J Gerontol A Biol Sci Med Sci., 2013.

polycythemia. This is a serious medical condition that requires treatment to prevent injury.

85. The clinical trial data submitted to the FDA for the approval of Testim, Testosterone Cypionate, and AndroGel showed that the use of exogenous testosterone resulted in nine percent of subjects experiencing hematocrit levels greater than 56% at some point during the study. A hematocrit level of 56% is significantly elevated above the normal range and qualifies as polycythemia. This is a level that puts the patient at serious risk for an adverse health consequence and requires immediate treatment and/or cessation of the testosterone therapy.

86. Elevated hematocrit is an independent risk factor for stroke and it interacts synergistically with elevated blood pressure. In a published study[4] the cohort for men with a hematocrit level greater than or equal to 51% had a more than doubling of the risk of stroke (RR=2.5), and among males in the cohort who were also hypertensive there was a nine-fold increase in the risk of stroke for those with hematocrit greater than or equal to 51%.

87. Elevated hematocrit is also an independent risk factor for adverse cardiovascular events. Using data from the Framingham Heart Study, researchers documented a strong, graded relationship between hematocrit level and the risk of developing heart failure. In 3,523 Framingham participants, aged 50-65, who were free of a history of heart failure at baseline and were followed prospectively for up to 20 years, individuals with a hematocrit level greater than or equal to 50% had almost double the risk of new-onset

[4] Wannamethee G1, Perry IJ, Shaper AG, Haematocrit, hypertension and risk of stroke. J Intern Med. 1994 Feb;235(2):163-8.

heart failure during follow-up, compared with those with a low hematocrit, even after adjustment for conventional risk factors for heart failure.[5]

88. In another study of 680 males conducted over 28 years in Finland, the data showed that men with a hematocrit level greater than or equal to 50% were 2.4 times more likely to die from coronary heart disease than men with hematocrit levels of less than 50%. Even after adjusting for established coronary risk factors, the increased risk remained 1.8-fold for the higher hematocrit cohort.[6]

89. In yet another large, prospective study[7] in Norway, the data show a hazard ratio of 1.25 per 5% rise in hematocrit. In a category-based analysis, a hematocrit level in the upper 20th percentile was found to be associated with a 1.5-fold increased risk of venous thrombosis, and a 2.4-fold increased risk of unprovoked venous thromboembolism compared to men whose hematocrit was in the lower 40th percentile.

90. An increase in the level of hematocrit also causes an increase in the viscosity of the blood. A 10.99% increase of hematocrit produces an increase of 1 unit relative viscosity, which means approximately a 20% increase in blood viscosity for a healthy individual.12[8] An increase in blood viscosity is a known risk factor for ischemic heart disease[9], and it can cause hypertension as blood pressure increase will be 20% or vasodilation will be 4.66% in radius for the physiologic compensation of 20% increased

[5] Coglianese, E., et al., Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. Am J Cardiol. Jan 15, 2012; 109(2): 241–245. Published online Oct 12, 2011

[6] Kunnas, T, et al., Hematocrit and the risk of coronary heart disease mortality in the TAMRISK study, a 28-year follow-up. Prev. Med. Volume 49, Issue 1, July 2009, Pages 45–47.

[7] Braekkan SK, Mathiesen EB,et al., Hematocrit and risk of venous thromboembolism in a general population. The Tromso study. Haematologica. 2010 Feb; 95(2):270-5.

[8] Cinar, Y., et al., Effect of hematocrit on blood pressure via hyperviscosity. Am J Hypertens. 1999 Jul;12(7):739-43.

[9] Yarnell, JW, et al., Fibrinogen, viscosity, and white blood cell count are major risk factors for ischemic heart disease. The Caerphilly and Speedwell collaborative heart disease studies. Circulation. 1991 Mar;83(3):836-44.

viscosity. Hypertension is a known cause of atherosclerosis, heart failure, and stroke. Testosterone makes blood thick and viscous, which, in turn, can cause numerous health risks and injuries for patients.

91. The major source of estradiol in men comes from the aromatization of testosterone (endogenous and/or exogenous) to estradiol. When men are given testosterone, either by application of an androgen gel or by injection, some of that testosterone is converted by the body (aromatized) to estradiol.[10] The increase of estradiol is in direct relation to the amount of the dose of exogenous testosterone delivered; the higher the dose of testosterone, the higher the level of serum estradiol.[11]

92. In data gathered from 2,197 men who participated in the Honolulu Aging Study from 1991-1993, and who were followed for thromboembolic and hemorrhagic events until 1998, there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower.[12] This study revealed that estradiol blood levels greater than 34.1 pg/mL resulted in this more than doubling of stroke incidence. As a source of embolism, the authors noted that the prevalence of atrial fibrillation rose significantly from 1.0 to 4.4% from the bottom to the top estradiol quintiles. Atrial fibrillation is a known cause of thrombus formation.

93. If men have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant, then the estradiol can interact with

[10] Glueck, CJ, et al., Thrombotic events after starting exogenous testosterone in men with previously undiagnosed familial thrombophilia. Trans. Res. Oct. 2011.
[11] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.
[12] Abbott, RD, et al., Serum Estradiol and Risk of Stroke in Elderly Men. Neurology 2007, 68:563-568.

the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones.[13]

94. In a study published 2006, blood levels of estradiol were measured in 313 men whose average age was 58. Carotid artery intima-media thickness was measured at baseline and then three years later. After adjusting for other risk factors, men with higher levels of estradiol suffered a worsening thickening of their carotid artery wall. This led the researchers to conclude, "circulating estradiol is a predictor of progression of carotid artery intima-media thickness in middle-aged men."[14] These findings of a positive association between serum estradiol levels and intima-media thickening supports the notion that estrogens, besides possibly increasing the risk for thrombosis and thereby cardiovascular events, also have an important impact on atherogenesis in men.

95. In a case control study of men in the Framingham cohort supra, serum estradiol levels were significantly increased in subjects with coronary heart disease.19[15]

96. Estradiol has a greater effect in the male heart through the regulation of gene expression that it does not in female hearts. This effect results in impaired contractile function of the heart in males with elevated levels of serum estradiol.[16] Impaired contractile function results in numerous cardiovascular injuries and disease.

97. A study published in 2007 compared blood levels of testosterone and estradiol in men suffering acute myocardial infarction (heart attack) with those who had previously suffered a heart attack. Sex hormones were measured in patients presenting with acute

[13] Glueck, CJ, et al., Testosterone, thrombophilia, thrombosis. Blood Coagulation and Fibrinolysis 2014, 25:00–00.
[14] Tivesten, A., et al., Circulating Estradiol is an Independent Predictor of Progression of Carotid Artery Intima-Media Thickness in Middle-Aged Men, J CLIN ENDOCRINOL METAB, November 2006, 91 (11): 4433-4437.
[15] Phillips GB, Castelli WP, Abbott RD, et al., Association of Hyperestrogenemia and Coronary Heart Disease in Men in the Framingham Cohort, Am J Med, 1983 74:863-869.
[16] Kararigas, G., et al., Transcriptome Characterization of Estrogen-Treated Human Myocardium Identifies Myosin Regulatory Light Chain Interacting Protein as a Sex-Specific Element Influencing Contractile Function, JACC Vol. 59, No. 4, January 24, 2012, 2012:410-7.

heart attack, patients with old heart attack, and patients with normal coronary arteries. The results showed significantly higher levels of estradiol in both groups of heart attack patients compared with those without coronary disease.[17] In another study, men admitted to the hospital with acute heart attacks whose levels of sex hormones were evaluated. Compared with control patients, estradiol levels in these heart attack patients were 180% higher, while bioavailable testosterone levels were nearly three times less than those of control patients.22[18]

98. High testosterone levels enhance acute myocardial inflammation, adversely affecting myocardial healing and early remodeling, as indicated by increased cardiac rupture, and possibly causing deterioration of cardiac function after MI, and, conversely, estrogen seems to have no significant protective effect in the acute phase after MI.23[19]

99. Thromboxane A2 (TXA2) is a vasoconstrictor and platelet pro-aggregatory agent that has been implicated in the pathogenesis of cardiovascular disease. Thromboxane A2has been unequivocally implicated in a range of cardiovascular diseases, owing to its acute and chronic effects in promoting platelet aggregation, vasoconstriction and proliferation. A study published in 1995 demonstrated that testosterone treatment was associated with a significant increase in the maximum platelet aggregation response and this effect may contribute to the thrombogenicity of androgenic steroids like testosterone.[20]

[17] Mohamad MJ, Mohammad MA, Karayyem M, Hairi A, Hader AA. Serum levels of sex hormones in men with acute myocardial infarction. Neuro Endocrinol Lett. 2007 Apr;28(2):182-6.
[18] Pugh PJ, Channer KS, Parry H, Downes T, Jone TH. Bio-available testosterone levels fall acutely following myocardial infarction in men: association with fibrinolytic factors. Endocr Res. 2002 Aug;28(3):161-73.
[19] Maria A. Cavasin , Zhen-Yin Tao , Ai-Li Yu , Xiao-Ping Yang; American Journal of Physiology - Heart and Circulatory Physiology Published 1 May 2006Vol. 290no. H2043-H2050DOI: 10.1152/ajpheart.01121.2005

[20] Ajayi, A., et al., Testosterone Increases Human Platelet Thromboxane A2 Receptor Density and Aggregation Responses. Circulation. 1995; 91: 2742-2747.

100. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

101. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels", in which a large cohort of men who used testosterone taken from a database of the Veteran's Administration was compared against a cohort of men who did not use testosterone. The data showed that among the cohort who used testosterone, the testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

102. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a comorbid condition. The conclusion of this published study was that the risk of myocardial infarction following initiation of testosterone therapy prescription is substantially increased.

103. In a study published in 2013[21], based on a systematic review and meta-analysis of placebo-controlled randomized trials of testosterone therapy among men lasting 12+ weeks reporting cardiovascular-related events, two reviewers independently searched, selected and assessed study quality with differences resolved by consensus. Additionally, two statisticians independently abstracted and analyzed data, and concluded that testosterone therapy increased the risk of a cardiovascular-related event. Their meta-analysis of the published literature also showed that the effect of testosterone therapy

[21] Xu, L., et al., Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials. BMC Medicine 2013, 11:108.

varied with source of funding. In trials not funded by the pharmaceutical industry the risk of a cardiovascular-related event on testosterone therapy was greater than in pharmaceutical industry funded trials. The study concluded that the existing body of published medical literature demonstrates that in trials not funded by the pharmaceutical industry, exogenous testosterone increased the risk of cardiovascular-related events, with corresponding implications for the use of testosterone therapy.

104. In some patient populations, testosterone use can increase the incidence of adverse events and death by over 500%.

105. Defendants had an obligation to comply with the law in the manufacture, design, marketing and sale of Testim, Testosterone Cypionate, and AndroGel.

5. Inadequate Warnings and Labeling

106. Defendants' marketing strategy has been to aggressively market and sell their products by misleading potential users and their physicians about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of their products.

107. Defendants successfully marketed Testim, Testosterone Cypionate, and AndroGel by undertaking "disease awareness" marketing campaigns. These campaigns sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low T."

108. Defendants' advertising programs sought to create the image and belief by consumers that the use of Testim, Testosterone Cypionate, and AndroGelwere safe methods of alleviating their symptoms, had few side effects and would not interfere with their daily

lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

109. Defendants promoted and marketed testosterone replacement therapy to physicians as a lifestyle drug that could treat a variety of symptoms caused by the normal aging process in males, including: erectile dysfunction; loss of libido; loss of athleticism; loss of muscle mass; fatigue; and mood swings. Defendants overstated the benefits of testosterone as a treatment for lifestyle changes associated with the aging process despite the fact that the drug was never FDA approved for these uses.

110. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Testim, Testosterone Cypionate, and AndroGel. Defendants deceived potential Testim, Testosterone Cypionate, and AndroGel users and their physicians by relaying positive information through the press, including Testim, Testosterone Cypionate, and AndroGel testimonials from retired professional athletes, and manipulating the definition of hypogonadism and statistics of its occurrence in men to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

111. Defendants concealed material relevant information from potential Testim, Testosterone Cypionate, and AndroGel users, and their physicians, and minimized user and prescriber concern regarding the safety of Testim, Testosterone Cypionate, and AndroGel, including but not limited to its known propensity to drastically increase hematocrit and estradiol in users.

112. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential risk of cardiac event, stroke, pulmonary embolism or other dangerous side effects related to blood clotting and falsely

represent that Defendants adequately tested Testim, Testosterone Cypionate, and AndroGel for all likely side effects. The Defendants also fail to warn and instruct regarding the importance of adequate monitoring of hematocrit and estradiol levels.

113. The prescribing information and medication guides for Testim, Testosterone Cypionate, and AndroGel contained within the package materials do not warn that the product may cause a significant increase in risk for stroke, pulmonary embolism, transient ischemic attack, cardiovascular disease, myocardial infarction, coronary heart failure, or any thromboembolic event not related to polycythemia.

114. The prescribing information and medication guide contained within the package materials also fail to instruct patients to tell their healthcare provider if they have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant. They also fail to adequately warn patients or physicians of the degree of enhanced risk presented by the presence of comorbid conditions or pre-existing heart disease, which have been proven to double the risk in men under the age of 65 who use testosterone therapy.

115. The prescribing information and medication guide contained within the package materials do warn that use of the product may result in increased red blood cell count, but do not instruct physicians or patients that use can increase a red blood cell count to the point that it more than doubles the risk for stroke, pulmonary embolism, ischemic heart disease, coronary heart failure, and myocardial infarction. The purported warning in regard to red blood cell count does not warn patients and their physicians that hematocrit levels can rise by as much as 10% above normal range, nor does it warn of the serious and life threatening risks that are associated with a red blood cell count that exceeds 50%,

including the fact that individuals with a hematocrit greater than or equal to 51% have a doubling of the risk of stroke, new-onset heart failure, and coronary heart disease.

116. The prescribing information and medication guide contained within the package materials do instruct physicians to re-evaluate their patient's hematocrit 3 to 6 months after starting treatment, but they fail to warn patients and their physicians that the product can cause dangerous increases in hematocrit much more rapidly, and also fail to instruct physicians to monitor their patient's hematocrit more frequently.

117. The prescribing information and medication guide contained within the package materials fail to warn that use of the product may result in elevated levels of estradiol. They do not instruct physicians to monitor estradiol levels, nor do they provide any guidance to physicians or patients regarding the significant health risks associated with elevated levels of serum estradiol in men, including the fact that there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower, and that estradiol blood levels greater than 34.1 pg/mL resulted in more than doubling of stroke incidence in men. There is also no warning that elevated serum estradiol levels resulting from use of the product can cause impairment of contractility of the heart.

118. The prescribing information and medication guide contained within the package materials do not warn that use of the product may result in the formation of deep vein thrombosis, pulmonary embolism, stroke, infarction, coronary heart failure, cardiovascular disease, or myocardial infarction caused by elevated levels of estradiol.

119. The prescribing information and medication guide contained within the package materials do not offer any warning of the very serious health risks for men over the age of 65 who use testosterone replacement therapy. There is no mention of the fact that there is a

doubling of the risk of heart attacks in men over the age of 65 who use testosterone replacement therapy, despite the fact that the data supporting this finding has been available for years. Instead, the label only states that the manufacturer lacks any information regarding the safety or efficacy of testosterone therapy for men over the age of 65. This absence of a warning fails to adequately advise and instruct patients and their physicians of the very serious health risks caused by the use of testosterone in this patient population.

120. In November of 2013, Rebecca Vigen, Colin I. O'Donnell, Anna E. Barón, Gary K. Grunwald, et al. published as article in the Journal of the American Medical Association entitled Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels ["Vigen Paper"].

121. The Vigen Paper concluded that: "Use of testosterone therapy in this cohort of veterans with significant medical comorbidities was associated with increased risk of mortality, MI, or ischemic stroke." In fact, testosterone therapy increased the risk of death, heart attack, and stroke by approximately 30%.

122. On January 29, 2014, William D. Finkle, Sander Greenland, Gregory K. Ridgeway John L. Adams, et al. published an article in PLOS ONE entitled Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men ["Finkle Paper"].

123. The Finkle Paper demonstrated an increased risk of heart attack in men over age 65 years, and in men younger than 65 years with a prior history of heart disease.

124. The increased incidence of heart attack and stroke was foreseeable at the time of the product launches of Testim, Testosterone Cypionate, and AndroGel.

125. On June 19, 2014, and in response to post-market reports of venous blood clots unrelated to polycythemia in testosterone users, the United States Food & Drug Administration (FDA) announced that it was requiring manufacturers of testosterone to include a general warning in the drug labeling of all approved testosterone products about the risk of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).

126. The marketing and promotion of these products to patients and physicians overstated their benefits by creating the impression that they were a safe and effective treatment for a variety of aging-related conditions and symptoms, for which it was not FDA approved. This is misleading and fails to adequately warn physicians and patients about the numerous, life-threatening health risks associated with use of the drug.

127. As a result of Defendants' advertising and marketing, and representations about their products, men in the United States pervasively seek out prescriptions for Testim, Testosterone Cypionate, and AndroGel. If Plaintiff and his physician had known the risks and dangers associated with Testim, Testosterone Cypionate, and AndroGel, the physician would not have prescribed nor would Plaintiff would have taken Testim or Testosterone Cypionate or AndroGel and consequently would not have been subject to its serious side effects; and/or, Plaintiff's physicians would have adequately monitored Plaintiff's hematocrit and estradiol levels, and, as a result, Plaintiff's injuries would have not otherwise have occurred.

6. Case Specific Facts

128. Plaintiff sought specific testing and treatment for "Low T" based upon the representations and medical information provided to him by Defendants through direct-to-consumer educational and information "Low T" awareness campaigns propagated by Defendants, Auxilium, et al.

129. Defendants sought to raise the awareness of physicians, including Plaintiff's physician, with respect to a condition denominated as "Low T," and to educate physicians about "Low T" and its treatment.

130. Defendants had a duty to warn prescribing physicians about the risks of testosterone use, including the risks of cardiovascular events and cerebrovascular accident.

131. Plaintiff's physician would not have prescribed Testim, Testosterone Cypionate, and AndroGel to this patient, Plaintiff, Christopher Chaudoir had he been advised of and adequately warned of the risks of adverse cardiovascular events caused by or increased with respect to the risk of harm presented by Testim, Testosterone Cypionate, and AndroGel.

132. On or about, March 1, 2008, Plaintiff commenced treatment with Testim, after being prescribed this medication by his physician, Dr. Hector A. Robles. Thereafter, from October of 2009 thru approximately September of 2012 Plaintiff was prescribed and applied AndroGel 1%, after which he received 1 ML injections of Testosterone Cypionate every two weeks from June 2013 thru approximately March 2014 when he experienced a heart attack.

133. Plaintiff's injuries, damages and losses were directly and proximately caused by or increased in the risk of harm by his use of testosterone.

134. Because of his use of Testim, Testosterone Cypionate, and AndroGel, Plaintiff suffered a myocardial infarction and has and will suffer the following past, present and future injuries, damages and losses:

    a. physical impairment and disability;

    b. loss of enjoyment of life;

    c. fear, fright, worry and concern;

    d. mental anguish, embarrassment and humiliation;

    e. economic loss and loss of earning capacity;

    f. requirement for medical monitoring relating to his injuries, including cerebrovascular and cardiovascular accident; and

    g. past, present and future medical expenses.

135. Plaintiff, Christopher Chaudoir, has incurred significant medical expenses as a result of the treatment he underwent to treat his injury, will incur future medical expenses as his injury is permanent, and his ability to labor and earn money has been impaired, he is at increased risk for future health problems and disability, and he suffers physical pain and mental anguish.

136. Defendants materially and deceptively misrepresented and mischaracterized the definition of hypogonadism to the Plaintiff and his physician.

137. Had Plaintiff and his physicians known the true risks associated with the use of testosterone medications, including Testim, Testosterone Cypionate, and AndroGel, he would not have consumed the Testim or Testosterone Cypionate or AndroGel, and/or would have been adequately monitored for its side effects, and as a result, would not have incurred the injuries or damages he did as a result of his use of Testim, Testosterone Cypionate, and AndroGel.

II. FEDERAL REQUIREMENTS

138. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq*.

139. With respect to the testosterone replacement drug Testim, Testosterone Cypionate, and AndroGel, Defendants, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs, including, but not limited to, one or more of the following violations:

a. The prescription drug Testim, Testosterone Cypionate, and AndroGel is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. The prescription drug Testim, Testosterone Cypionate, and AndroGel is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from, or its quality or purity falls below, the standard set forth in the official compendium for Testim and Testosterone Cypionate, and such deviations are not plainly stated on its labels.

c. The prescription drug Testim, Testosterone Cypionate, and AndroGel is misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.

d. The prescription drug Testim, Testosterone Cypionate, and AndroGel is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. §352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The prescription drug Testim, Testosterone Cypionate, and AndroGel is misbranded pursuant to 21 U.S.C. §352 because the labeling does not (i) bear adequate directions for use, and/or (ii) bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. The prescription drug Testim, Testosterone Cypionate, and AndroGel is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage, manner, or with the frequency or duration prescribed,

recommended, or suggested in the labeling thereof.

g. The prescription drug Testim, Testosterone Cypionate, and AndroGeldoes not contain adequate directions for use pursuant to 21 CFR §201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of:

(1) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used;

(2) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions;

(3) frequency of administration or application;

(4) duration or administration or application; and/or

(5) route or method of administration or application.

h. Defendants violated 21 CFR §201.56 because the labeling was not informative and accurate.

i. The prescription drugs Testim, Testosterone Cypionate, and AndroGel are misbranded pursuant to 21 CFR §201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. Defendants violated 21 CFR §201.57 by failing to provide information that is important to the safe and effective use of the drug, including the potential of Testim, Testosterone Cypionate, and AndroGel to cause or exacerbate cardiovascular disease and the need for regular and consistent monitoring to ensure that a potentially fatal cardiac condition has not developed.

k. Defendants violated 21 CFR §201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drugs Testim, Testosterone Cypionate, and AndroGel.

l. Defendants violated 21 CFR §201.57 because the safety considerations regarding the prescription drug Testim, Testosterone Cypionate, and AndroGel are such that the drug should be reserved for certain situations, and the Defendant failed to state such information.

m. The prescription drug Testim, Testosterone Cypionate, and AndroGel is

mislabeled pursuant to 21 CFR §201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

n. The prescription drug Testim, Testosterone Cypionate, and AndroGel is mislabeled pursuant to 21 CFR §201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

o. Defendants violated 21 CFR §201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Testim, Testosterone Cypionate, and AndroGel and other drugs in the same pharmacologically active and chemically related class.

p. Defendants violated 21 CFR §201.57 because the possibility that a patient could develop cardiovascular disease and other adverse reactions significantly more severe than the other reactions listed in the adverse reactions, and yet Defendants failed to list the development of same before the other adverse reactions on the labeling of the prescription drug Testim, Testosterone Cypionate, and AndroGel.

q. The prescription drug Testim, Testosterone Cypionate, and AndroGel is mislabeled pursuant to 21 CFR §201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. The prescription drug Testim, Testosterone Cypionate, and AndroGel violates 21 CFR §210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and meets the quality and purity characteristics that it purports or is represented to possess.

s. The prescription drug Testim, Testosterone Cypionate, and AndroGel violates 21 CFR §210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. The prescription drug Testim, Testosterone Cypionate, and AndroGel violates 21 CFR §211.165 because the test methods employed by Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. The prescription drug Testim, Testosterone Cypionate, and AndroGel violates 21 CFR §211.165 in that the prescription drug fails to meet established standards or specifications and any other relevant quality control criteria.

v. The prescription drug Testim, Testosterone Cypionate, and AndroGel violates 21 CFR §211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Testim, Testosterone Cypionate, and AndroGel were not followed.

w. The prescription drug Testim, Testosterone Cypionate, and AndroGel violates 21 CFR §310.303 in that the prescription drug Testim, Testosterone Cypionate, and AndroGel is not safe and effective for its intended use.

x. Defendants violated 21 CFR §310.303 because Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug Testim, Testosterone Cypionate, and AndroGel as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.

z. Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Testim, Testosterone Cypionate, and AndroGel, and evaluating the cause of the adverse event.

aa. Defendants violated 21 CFR §§310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. Defendants violated 21 CFR §§310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

cc. Defendants violated 21 CFR §§310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow-up."

dd. Defendants violated 21 CFR §312.32 because it failed to review all information relevant to the safety of the prescription drug Testim, Testosterone Cypionate, and AndroGel or otherwise received by the Defendant from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. Defendants violated 21 CFR §314.80 by failing to provide periodic reports to the FDA containing

(1) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval,

(2) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or

(3) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. Defendants violated 21 CFR §314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

140. Defendants failed to meet the standards of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as Christopher Chaudoir. These federal requirements constitute sources of legal duties on the part of Defendants, Auxilium Pharmaceuticals, Inc., DPT Laboratories, Inc.; AbbVie, Inc., Abbott Laboratories, Inc.; Actavis PLC, and Actavis, Inc. f/k/a: Watson Pharmaceuticals, Inc., which were substantial factors in causing harm to Plaintiff, Christopher Chaudoir and renders all Defendants liable herein for damages under Louisiana law.

III. CAUSES OF ACTION

Count One – Strict Products Liability – Failure to Warn

141. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

142. The Defendants are liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement of Torts 2d.

143. The Testim, Testosterone Cypionate, and AndroGel manufactured and/or supplied by Defendants were defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks.

144. Defendants failed to adequately warn consumers and/or their health care providers that Testim, Testosterone Cypionate, and AndroGel could cause heart attacks, strokes, pulmonary embolism, cardiovascular events and blood clots.

145. Defendants failed to adequately warn consumers and/or their health care providers that while a patient was taking Testim, Testosterone Cypionate, and AndroGel it was necessary to frequently monitor hematocrit and estradiol levels to prevent heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots.

146. The Testim, Testosterone Cypionate, and AndroGel manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of Testim, Testosterone Cypionate, and AndroGel, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

147. As a direct and proximate result of Plaintiff's reasonably anticipated use of Testim, Testosterone Cypionate, and AndroGel as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

Count Two – Negligence

148. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

149. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Testim, Testosterone Cypionate, and AndroGel.

150. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of Testim, Testosterone Cypionate, and AndroGel to cause, or increase the harm of among other severe injuries, myocardial infarction, cerebrovascular accident, deep vein thrombosis and its sequelae, pulmonary embolism, and sudden cardiovascular death.

151. Defendants had a duty of care when they undertook to provide comprehensive medical information to consumers and patients concerning "Low T" as a medical diagnostic entity; and, to educate and inform consumers and patients about "Low T;" and, to provide consumers and patients with the means for self-diagnostic screening and in-home testing for "Low T."

152. Defendants had a duty to disclose to physicians and healthcare providers the causal relationship or association of Testim, Testosterone Cypionate, and AndroGel to heart attack, stroke, deep vein thrombosis and its sequelae, pulmonary embolism, and sudden cardiac death.

153. Defendants' duty of care owed to consumers and patients included providing accurate, true, and correct information concerning:

- hypogonadism and its diagnostic criteria;
- the FDA-approved indications for the clinical use of the Testim, Testosterone Cypionate, and AndroGel product;
- the clinical safety and effectiveness profiles of Testim, Testosterone Cypionate, and AndroGel;
- appropriate, complete, and accurate warnings concerning the adverse effects of Testim, Testosterone Cypionate, and AndroGel, including heart attack, stroke, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death; and,
- Notice of after acquired knowledge regarding Adverse Event Reports (AER) and scientific reports regarding risks associated with use of Testosterone Replacement Therapy drugs.

154. At all times herein mentioned, Defendants breached their duty of care when they negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold Testim, Testosterone Cypionate, and AndroGel and failed to adequately test and warn of the risks and dangers of Testim, Testosterone Cypionate, and AndroGel as described herein.

155. The Defendants negligently and carelessly disregarded the applicable regulations and industry standards regarding the prohibition against off-label marketing, misbranding and label expansion, and as a result millions of men, including the Plaintiff, were prescribed Testim, Testosterone Cypionate, and AndroGel unnecessarily, and therefore needlessly exposed to serious health risks for which there were no or inadequate warnings.

156. At all times material hereto, Defendants sought to mislead and misinform physicians concerning the FDA-approved uses for Testim, Testosterone Cypionate, and AndroGel, including Plaintiff's prescribing physician. Specifically, the FDA had not approved

Testim or Testosterone Cypionate, or AndroGel or any other testosterone-containing preparation for the treatment of "Low T."

157. At all times material hereto, Defendants recklessly, intentionally, and knowingly detailed and promoted the testosterone-containing product Testim, Testosterone Cypionate, and AndroGel with the intent that men be prescribed testosterone therapy by physicians for "off-label" clinical indications.

158. Despite the fact that Defendants knew or should have known that Testim, Testosterone Cypionate, and AndroGel caused unreasonable, dangerous side effects, Defendants continued to market Testim, Testosterone Cypionate, and AndroGel to consumers including Plaintiff, when there were safer alternative methods and/or no need to treat conditions such as loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions that Testim, Testosterone Cypionate, and AndroGel marketing materials claim were caused by "Low T".

159. At all times material hereto, Defendants misbranded the Testim, Testosterone Cypionate, and AndroGel products on an on-going and continuous basis, and failed to warn physicians and patients that Testim, Testosterone Cypionate, and AndroGel were not approved for the treatment of "Low T" or age-related declines in testosterone or age-related symptoms in men.

160. Defendants failed to disclose to physicians, consumers, and patients the known cardiovascular and cerebrovascular risks causally associated with Testim, Testosterone Cypionate, and AndroGel.

IV. COROLLARY STATE CLAIMS

FIRST CAUSE OF ACTION

Construction or Composition Defect under La. R.S. 9:2800.55

161. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

162. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Testim, Testosterone Cypionate, and AndroGel.

163. At all times material to this action, Testim, Testosterone Cypionate, and AndroGel were expected to reach, and did reach, consumers in the State of Louisiana and throughout the United States, including Christopher Chaudoir, without substantial change in the condition in which it was sold.

164. At all times material to this action, Testim, Testosterone Cypionate, and AndroGel were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Testim, Testosterone Cypionate, and AndroGel contained manufacturing defects which rendered the subject product unreasonably dangerous;

b. The subject products' manufacturing defects occurred while the products were in the possession and control of Defendants;

c. The subject products were not made in accordance with Defendants' specifications or performance standards; and

d. The subject products' manufacturing defects existed before they left the control of Defendants.

165. The subject products manufactured and/or supplied by Defendants were defective in construction or composition in that, when they left Defendants' hands, they deviated in a material way from Defendants' manufacturing performance standards and/or differed from otherwise identical products manufactured to the same design formula. In particular, the products are not safe, have numerous and serious side effects, and cause severe and permanent injuries including, but not limited to, developing cardiovascular disease, strokes, heart attacks and myocardial infarctions. The products were unreasonably dangerous in construction or composition as provided by La. R.S. 9:2800.55.

SECOND CAUSE OF ACTION

Design Defect under La. R.S. 9:2800.56

166. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

167. Testim, Testosterone Cypionate, and AndroGel are defective in their design or formulation in that they are not reasonably fit, suitable, or safe for their intended purpose and/or their foreseeable risks exceed the benefits associated with their design and formulation. The subject products were unreasonably dangerous in design as provided by La. R.S. 9:2800.56.

168. At all times material to this action, Testim, Testosterone Cypionate, and AndroGel were expected to reach, and did reach, consumers in the State of Louisiana and throughout the United States, including Christopher Chaudoir, without substantial change in the condition in which they were sold.

169. At all times material to this action, Testim, Testosterone Cypionate, and AndroGel were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at

the time they were placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Testim, Testosterone Cypionate, and AndroGel contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Christopher Chaudoir to risks that exceeded the benefits of the subject product, including, but not limited to, permanent personal injuries including, but not limited to, developing cardiovascular disease, strokes, myocardial infarctions, and other serious injuries and side effects;

b. When placed in the stream of commerce, Testim, Testosterone Cypionate, and AndroGel were defective in design and formulation, making the use of Testim, Testosterone Cypionate, and AndroGel more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat testosterone deficiencies;

c. The design defects of Testim, Testosterone Cypionate, and AndroGel existed before they left the control of Defendants;

d. Testim, Testosterone Cypionate, and AndroGel were insufficiently tested;

e. Testim, Testosterone Cypionate, and AndroGel caused harmful side effects that outweighed any potential utility; and

f. Testim, Testosterone Cypionate, and AndroGel were not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Christopher Chaudoir, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

170. In addition, at the time the subject products left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Christopher Chaudoir's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Christopher Chaudoir's injuries without substantially impairing the product's utility.

THIRD CAUSE OF ACTION

Inadequate Warning under La. R.S. 9:2800.57

171. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

172. Testim, Testosterone Cypionate, and AndroGel were defective and unreasonably dangerous when they left the possession of Defendants in that they contained warnings insufficient to alert consumers, including Christopher Chaudoir, of the dangerous risks and reactions associated with the subject products, including but not limited to their propensity to cause permanent physical injuries including, but not limited to, developing cardiovascular disease, strokes, heart attacks, myocardial infarcts, and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for testosterone deficiencies. Thus, the subject products were unreasonably dangerous because an adequate warning was not provided pursuant to La. R.S. 9:2800.57.

173. The subject products manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury and/or death.

174. Christopher Chaudoir was prescribed and used the subject products for their intended purpose.

175. Christopher Chaudoir could not have discovered any defect in the subject products through the exercise of reasonable care.

176. Defendants, as manufacturers and/or distributors of the subject prescription products, are held to the level of knowledge of an expert in the field.

177. Defendants, the manufacturer and/or distributor of the subject prescription products, are held to a level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

178. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

179. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to, developing serious injuries, side effects and death.

180. Christopher Chaudoir, individually and through his prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

181. Defendants had a continuing duty to warn Christopher Chaudoir of the dangers associated with the subject product, even if acquired after the products were placed into the stream of commerce.

182. Each time Plaintiff, Christopher Chaudoir, was prescribed Testim and/or Testosterone Cypionate, and/or AndroGel and given an injection, the packaging included a "Prescribing Information" specification sheet and/or a "Medication Guide" provided by Defendants.

183. Neither the Prescribing Information sheet nor the Medication Guide contain a reference to the actual dangerous risks and reactions associated with the use of Testim, Testosterone Cypionate, and AndroGel, including but not limited to its propensity to cause permanent physical injuries including, but not limited to, developing cardiovascular disease, strokes,

heart attacks, myocardial infarcts, and other serious injuries, side effects, and death.

184. The warnings contained in both the "Prescribing Information" sheet and the "Medication Guide" which accompanied the product, were holistically inadequate and, in and of themselves, rendered the product unreasonably dangerous in normal use.

185. Neither Mr. Chaudoir nor his prescribing physician received adequate warnings regarding the tremendous risks associated with the use of Testim, Testosterone Cypionate, and AndroGel. Had Defendants not breached their duty to provide fully accurate and adequate warnings of the risks associated with the use of this products, Christopher Chaudoir would not have used Testim, Testosterone Cypionate, and AndroGel or he would have discontinued its use had Defendants, provided adequate warnings after he began using Testim, Testosterone Cypionate, and AndroGel.

FOURTH CAUSE OF ACTION

Breach of Express Warranty under La. R.S. 9:2800.58

186. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

187. Defendants expressly represented to Christopher Chaudoir, other consumers, and the medical community as a whole that Testim, Testosterone Cypionate, and AndroGel were safe and fit for their intended purposes, were of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

188. Testim, Testosterone Cypionate, and AndroGel do not conform to Defendants' express representations because they are not safe, have numerous and serious side effects, and cause severe and permanent injuries, including, but not limited to, developing cardiovascular disease, heart attacks, strokes, myocardial infarcts and other serious injuries and side effects.

189. 1At the time of the making of these express warranties, Defendants knew, or in the exercise of reasonable care should have known, of the purpose for which the subject products were to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject products were unreasonably dangerous because they failed to conform to an expressed warranty of Defendants as provided by La. R.S. 9:2800.58.

190. At the time of the making of these express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject products were not safe and fit for their intended use. To the contrary, Defendants knew or in the exercise of reasonable care should have known that Testim, Testosterone Cypionate, and AndroGel produce serious injuries to the user.

191. At all relevant times Testim, Testosterone Cypionate, and AndroGel did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

192. Prior to the time that Testim, Testosterone Cypionate, and AndroGel were used by Plaintiff, Christopher Chaudoir, Defendants impliedly warranted to Mr. Chaudoir and his prescribing physician that Testim, Testosterone Cypionate, and AndroGel were of merchantable quality and safe and fit for the use which Defendants, in concert with other manufacturers, promoted and warranted.

193. Plaintiff, Christopher Chaudoir, was unskilled in research, design and manufacture of medical products and prescription drugs and reasonably relied entirely upon the skill, judgment and warranties of the Defendants in using Testim, Testosterone Cypionate, and AndroGel intramuscular injections.

194. Christopher Chaudoir, other consumers, and the medical community at large relied upon Defendants' express and implied warranties.

195. As a result of the aforementioned breaches of express and implied warranties by Defendants: Auxilium Pharmaceuticals, Inc.; DPT Laboratories, Ltd.; AbbVie Inc., Abbott Laboratories Inc., Actavis PLC and Actavis, Inc. f/k/a: Watson Pharmaceuticals, Inc., Plaintiff, Christopher Chaudoir, suffered foreseeable and foreseen injuries, damages and losses.

FIFTH CAUSE OF ACTION

Redhibition

196. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

197. The subject products contain a vice or defect which renders them useless or their use so dangerous that buyers would not have purchased them.

198. Defendants sold and promoted Testim, Testosterone Cypionate, and AndroGel, which Defendants placed into the stream of commerce. Under Louisiana law, sellers warrant buyers against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520. The subject products sold and promoted by Defendants, possess a redhibitory defect because they were not manufactured and marketed in accordance with industry standards and/or were unreasonably dangerous, as described above, which renders the subject products useless or so inconvenient that it must be presumed that a buyer would not have bought the subject products had he known of the defect. Pursuant to La. C.C. art. 2520, Plaintiff is entitled to obtain a rescission of the sale of the subject product.

199. The subject product alternatively possesses a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or

is unreasonably dangerous, as described above, which diminishes the value of the subject product so that it must be presumed that a buyer would still have bought it but for a lesser price. In this instance, Plaintiff is entitled to a reduction of the purchase price.

200. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect, and thus, are liable to Plaintiff for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product and attorneys' fees. As the manufacturer of the subject product, under Louisiana law, Defendants are deemed to know that Testim, Testosterone Cypionate, and AndroGel possessed redhibitory defects. La. C.C. art. 2545.

Punitive Damages Allegations

201. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

202. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other Testim, Testosterone Cypionate, and AndroGel users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Testim, Testosterone Cypionate, and AndroGel. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

203. Prior to the manufacture, sale, and distribution of Testim, Testosterone Cypionate, and AndroGel, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication

would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Testim, Testosterone Cypionate, and AndroGel.

204. Despite their knowledge, Defendants, acted through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Testim, Testosterone Cypionate, and AndroGel and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Testim, Testosterone Cypionate, and AndroGel. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Testim, Testosterone Cypionate, and AndroGel knowing these actions would expose persons, like Christopher Chaudoir, to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

205. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for Plaintiff's safety, entitling Plaintiff to exemplary damages.

DEMAND FOR JURY TRIAL

206. Plaintiff, Christopher Chaudoir, is entitled to and hereby demands a jury trial on all claims so triable in this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, CHRISTOPHER CHAUDOIR, prays for judgment against the Defendants: AUXILIUM PHARMACEUTICALS, INC., DPT LABORATORIES, LTD.; ABBVIE, INC.; ABBOTTLABORATORIES, INC.; ACTAVIS PLC; AND ACTAVIS, INC. F/K/A/ WATSON PHARMACEUTICALS, INC., jointly, severally and *in solido* for all elements and items of general and special damages recoverable at law or in equity in amounts which are reasonable in the premises, including but not limited to:

a. Actual damages to Plaintiff incidental to Christopher Chaudoir's purchase and use of Testim, Testosterone Cypionate, and AndroGel in an amount to be determined at trial;

b. General damages in an amount that will conform to proof at time of trial;

c. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

d. Loss of earnings and impaired earning capacity according to proof at the time of trial;

e. Medical expenses, past and future, according to proof at the time of trial;

f. For past and future physical pain and disability, according to proof;

g. For past and future mental and emotional distress, according to proof;

h. For punitive or exemplary damages according to proof;

i. Reasonable attorneys' fees and costs to Plaintiff as provided by law; and

j. Restitution, disgorgement of profits, and other equitable relief;

k. Injunctive relief;

l. Pre-Judgment and post-judgment interest to Plaintiff;

m. All costs and expenses of this litigation;

n. Trial by jury on all issues herein and

o. Such other relief as the Court deems necessary, just and proper.

Dated: 1/29/2015

Respectfully submitted,

Domengeaux Wright Roy Edwards & Colomb, LLC

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